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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,742	09/17/2003	Magnus Bolmsjo	211.313	4686

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EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
09/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,742	BOLMSJO ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40 and 44-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40 and 44-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *28 May 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al. (US Patent 6,494,855) in view of Anderson et al. (US Patent 4,813,925).

4. Regarding claim 1, Rioux discloses an indwelling catheter to drain urine from a bladder to a location adjacent to a urinary sphincter muscle in a urinary tract which also includes a urinary canal extending from the sphincter muscle to an exterior opening, comprising:

a main body having a distal end, a proximal end and a length sufficient to position the distal end within the bladder and to position the proximal end adjacent to and distal of the sphincter muscle within the urinary tract, the main body defining an

urine drainage interior passageway extending from the distal end to the proximal end (column 4, lines 52-57 and Fig. 3, first tubular segment 10);

a balloon attached to the distal end of the main body, the balloon expandable in size within the bladder to maintain the distal end in the bladder and restrain the main body against proximal movement within the urinary tract from a use position, the use position locating the distal end of the main body in the bladder and the proximal end of the main body adjacent to and distal of the sphincter muscle (column 7, lines 40-42 and Fig. 3, inflatable balloon 1); and

an inflation tube having a distal end, a proximal end and a length extending between the distal end proximal ends, the distal end connected to the main body, the length sufficient to extend from the main body through the urinary canal to the exterior opening when the main body is in the use position, the inflation tube and the main body defining an inflation passageway extending from the proximal end of the inflation tube to the balloon through which to deliver inflation fluid for expanding the balloon (column 7, lines 42-47 and Fig. 3, tube 3 connected to inflatable balloon 1).

Rioux discloses the invention as substantially claimed, see above. However, Rioux lacks a coiled section of an inflation tube as claimed [claim 1]. Anderson discloses a ureteral stent for draining between a renal pelvis and bladder, which solves the problem of draining urine through an obstructed ureter (col. 1, lines 5-14, col. 3, lines 12-16, Fig. 1, ureteral stent 10). It is the Examiner's position that Anderson is analogous art, since both Rioux and Anderson solve the problem of draining urine through an obstructed urinary passage. Anderson further discloses a coiled section of

ureteral stent (col. 1, lines 12-16, 43-51, Figs. 1-3, coiled section 12 comprising coils 18). Anderson provides the advantages of resisting migration (col. 1, lines 62-65) and supporting any collapsed portions of a urinary lumen, in this case a ureter (col. 5, lines 38-46). One of ordinary skill in the art could have modified the inflation tube as taught by Rioux, by forming it as a coil or helix as taught by Anderson, with a reasonable expectation of success.

To clarify, Rioux teaches an inflation tube, while Anderson gives an example of a coiled restraining device. A coiled tube would have performed the same function of anchoring a urinary lumen as taught by Anderson. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux as discussed with the coiled section as taught by Anderson in order to resist migration and supporting any collapsed portions of a urinary lumen.

Examiner notes that coils are widely used in the urinary catheter arts for preventing migration or maintaining lumens in an open state. In a second example, Norton et al. (US Patent 4,531,933) discloses a ureteral stent (col. 2, lines 33-36, Figs. 1-2, ureteral stent 10) further comprising coiled sections (col. 2, lines 50-58, Fig. 2, short helical coil configuration 14 and longer coil 15). Norton also discloses the coiled sections as providing the advantage of preventing migration (col. 3, lines 12-17).

As a third example, Huxel et al. (US Patent Application Publication No. 2002/0002399) discloses a stent (¶ [0041], Figs. 1-4, stent 10) placed within the urinary tract having coils (¶ [0026], Fig. 3, coils 20). Here also, Huxel provides the advantage of maintaining the patency of a body lumen (¶ [0014]).

5. Regarding claims 2-4, 6 and 7, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a coiled section as claimed [claims 2-4, 6 and 7]. Anderson discloses a coiled section of a stent resilient in a transverse dimension and in a longitudinal dimension (col. 3, lines 27-30, stent 10 slightly extensible or contractible; and col. 4, lines 65-68, coiled section 12 reforming to coil shape during implanting). Therefore it naturally follows that each of coils 18 in coiled section 12 as taught by Anderson are both separately and collectively resilient in both a transverse and a longitudinal dimension.

Anderson provides the advantages of resisting migration and supporting any collapsed portions of a urinary lumen as discussed for claims 1 and above. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux as discussed with the coiled section of a urethral stent as taught by Anderson in order to resist migration and support any collapsed portions of a urinary lumen.

Regarding the limitation of decreasing in a transverse dimension upon elongation in a longitudinal dimension, Examiner notes that this property necessarily follows from a coil shape. When a coil shape is elongated in a longitudinal dimension, it will decrease in a transverse dimension.

6. Regarding claim 5, Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a coiled section comprising a plurality of individual adjacent coils each formed by the inflation tube as claimed [claim 5]. Anderson discloses a coiled section comprising a plurality of individual adjacent coils (col. 1, lines

12-16, 43-51, Figs. 1-3, coiled section 12 comprising coils 18). Regarding rationale and motivation, see discussion of claim 1 above.

7. Regarding claims 8 and 9, Rioux discloses the invention substantially as claimed, including a main body having an outer or exterior transverse dimension. See above. However, Rioux lacks a coiled section as claimed [claims 8 and 9]. Anderson discloses a coiled section, as discussed for claim 1 above, including an outer transverse dimension and a center opening. In modifying the invention of Rioux in view of Anderson, the main body as taught by Rioux is surrounded by the coil as taught by Anderson. Therefore, the combined invention demonstrates both:

[8] an outer transverse dimension of the coiled section greater than the outer transverse dimension of the main body; and

[9] an inner transverse dimension of the coiled section substantially the same as the exterior transverse dimension of the main body.

An outer transverse dimension of a coiled section needs to be greater than the outer transverse dimension of the main body in order to be placed in a surrounding manner. In other words, this property naturally follows from placing a coiled section about a main body. Also, Anderson provides the advantage of compact design, which conserves space inside a physiological lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux as discussed with the coiled section having an outer or exterior transverse dimension as taught by Anderson in order to conserve space.

8. Claims 10-16, 19-27, 30-37, 40 and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al. (US Patent 6,494,855) in view of Anderson et al. (US Patent 4,813,925), further in view of Devonec (US Patent 6,290,666).

9. Regarding claims 10-16, 19-27, 30, 31, 35-37, 40 and 45-47, Rioux in view of Anderson discloses the invention substantially as claimed, see above. However, Rioux in view of Anderson lacks an insertion tool and cord as claimed [claims 10-16 and 19]. Rioux discloses a "pusher" used for placing a main body (col. 9, lines 23-30), although the disclosure is silent regarding its structure. In other words, the "pusher" of Rioux suggests the structure of an insertion tool, although Rioux is silent regarding the structure of a length sufficient to position its first end within a urinary tract. Devonec discloses an endo-urethral prosthesis placeable without endoscopic or radiological checks (col. 2, lines 36-40, col. 3, lines 17-24) further comprising:

[10, 20] an insertion tool for connection to the indwelling catheter to move the indwelling catheter within the urinary tract to the use position (col. 6, lines 13-31, especially lines 16, 26, Figs. 8a, 8b, 9-12, mandrel 60 and pusher 63),

[10, 20] the insertion tool having first and second opposite ends and a length sufficient to position the first end within the urinary tract distal of the sphincter muscle while the second end is at the exterior of the urinary canal (col. 6, lines 48-54, Fig. 9, assembly placed into bladder 2). To clarify, the invention of Rioux in view of Anderson as discussed is modified with the insertion tool as taught by Devonec.

Additionally, Devonec discloses:

[10, 20] an insertion tool extending through the center opening of a coiled section (cols. 5-6, lines 53-58, 66-2, Fig. 13, coil 52);

[11] an insertion tool having an exterior transverse dimension substantially the same as the exterior transverse dimension of the main body (Figs. 8a, 9, 10, pusher 63 and tubular element 11 having substantially same exterior transverse dimensions);

[12, 21] a separable connection between the main body and the insertion tool to permit disconnection of the indwelling catheter and the insertion tool upon locating the indwelling catheter in the use position (col. 6, lines 13-31, especially lines 16-25, Fig. 8b, mandrel 60 engaging prosthesis 8);

[13, 22] a separable connection retaining the main body to the insertion tool to permit movement of the insertion tool and the indwelling catheter as a unit when positioning the indwelling catheter in the use position (col. 6, lines 48-54, Fig. 8a, mandrel 60 and pusher 63 joined to prosthesis 8, forming assembly for insertion into bladder 2);

[13, 22] the separable connection permitting separation of the indwelling catheter and the insertion tool in response to continued proximal movement of the insertion tool when the expanded balloon restrains the main body against proximal movement from the use position (col. 6, lines 59-4, Figs. 9-12, withdrawing mandrel 60 and pusher 63 from prosthesis 8. To clarify, the invention of Rioux is relied upon for a balloon as discussed, and is modified with the insertion tool as taught by Devonec.);

[14, 25, 35] a separable connection including a selectively disconnectable bridging structure extending between the main body and the insertion tool (col. 6, lines 48-54, Fig. 8a, mandrel 60 within pusher 63);

[15, 26, 36] a selectively disconnectable bridging structure comprising a cord which extends between the main body and the insertion tool when the bridging structure connects the main body to the bridging structure (col. 5, lines 36-39, cols. 6-7, lines 63-4, Figs. 8a, 8b, 9-12, removal thread 14 extending between prosthesis 8 and mandrel 60 and pusher 63);

[15, 26, 36] the extension of the cord between the main body and the insertion tool is eliminated when the bridging structure is disconnected (Fig. 12, mandrel 60 and pusher 63 removed);

[16, 19, 27, 30, 37, 40] the insertion tool defines an interior channel extending between the first and second opposite ends of the insertion tool (col. 6, lines 13-31, especially lines 16, 26, Figs. 8a, 8b, 9-12, both mandrel 60 and pusher 63 comprising hollow tubes); and

[16, 19, 27, 30, 37, 40] the interior channel of the insertion tool is in fluid communication with the interior passageway of the main body when the insertion tool is connected to the indwelling catheter at the separable connection (col. 6, lines 13-31, especially lines 16-25, Figs. 8a, 8b, 9-12, mandrel 60 placed within prosthesis 8);

[23, 24, 45] the insertion tool is removable from within the coiled section in response to a predetermined amount of proximal movement of the insertion tool in the urinary canal relative to the main body after separation at the separable connection, and

the coiled section permits substantially unimpeded proximal movement of the insertion tool within the coiled section after separation at the separable connection (col. 6, lines 59-4, Figs. 9-12, mandrel 60 and pusher 63 withdrawn from prosthesis 8);

[31, 47] the coiled section maintains a portion of the inflation tube between the coiled section and the proximal end of the main body substantially in alignment with a portion of the insertion tool during movement of the indwelling catheter and the insertion tool as a unit within the urinary tract to the use position (col. 6, lines 13-31, especially lines 22-25, mandrel 60 inserted within prosthesis 8; also aligning with eyelet 62a);

[46] the coiled section permits proximal movement of the insertion tool within the coiled section after separation of the catheter and tool main bodies at the separable connection (col. 6, lines 59-4, Figs. 9-12, mandrel 60 and pusher 63 capable of withdrawing from prosthesis 8).

Devonec provides the advantage of rapidly and accurately inserting a urinary prosthesis (cols. 6-7, lines 63-4, 54-62, quasi-automatic positioning). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux in view of Anderson as discussed with the insertion tool and cord as taught by Devonec in order to rapidly and accurately insert a urinary prosthesis.

10. Regarding claims 32 and 48, Rioux discloses an indwelling catheter for use with a syringe having a nozzle, further comprising a valve assembly connected to the proximal end of the inflation tube, the valve assembly including a receptacle by which to connect the nozzle of the syringe for transferring inflation fluid from the syringe into the

inflation passageway for inflating the balloon (column 7, lines 40-48 and Fig. 3, check valve 22 and inflation source 8 comprising a syringe). Since Fig. 3 depicts check valve 22 and inflation source 8 as connected, it naturally follows that a syringe has a nozzle, and check valve 22 comprises a receptacle by which to connect the nozzle of the syringe.

11. Regarding claims 33 and 44, Rioux in view of Anderson in view of Devonec discloses the invention as substantially claimed. To clarify, Rioux discloses a main body and inflation tube. Anderson discloses a coiled section, and the inflation tube of Rioux is modified in view of the coiled tube as taught by Anderson. Devonec discloses an insertion tool having a substantially equal diameter to a main body. Devonec discloses an insertion tool having an exterior surface (Figs. 8a, 8b, 9-12, pusher 63 having exterior surface). The invention of Rioux in view of Anderson modified with the insertion tool as taught by Devonec substantially forms an inflation tube extending along the exterior surface of an insertion tool when the main body is connected to the insertion tool. Regarding rationale and motivation, see discussion of claim 10 above.

12. Regarding claim 34, Rioux discloses an assembly of an indwelling catheter used to drain urine from a bladder to a location adjacent to a urinary sphincter muscle in a urinary tract which also includes a urinary canal extending from the sphincter muscle to an exterior opening, the assembly comprising:

a main body of the indwelling catheter, the catheter main body having a distal end, a proximal end and a length sufficient to position the distal end within the bladder and to position the proximal end adjacent to and distal of the sphincter muscle within the

urinary tract, the catheter main body defining an urine drainage interior passageway extending from the distal end to the proximal end (column 4, lines 52-57 and Fig. 3, first tubular segment 10);

a balloon attached to the distal end of the catheter main body, the balloon expandable in size within the bladder (column 7, lines 40-42 and Fig. 3, inflatable balloon 1);

an inflation tube having a distal end, a proximal end and a length extending between the distal and proximal ends, the distal end connected to the catheter main body, the length sufficient to extend from the catheter main body through the urinary canal to the exterior opening when the indwelling catheter is located in the use position, the inflation tube and the catheter main body defining an inflation passageway extending from the proximal end of the inflation tube to the balloon through which to deliver inflation fluid for expanding the balloon (column 7, lines 42-47 and Fig. 3, tube 3 connected to inflatable balloon 1);

Rioux discloses the invention as substantially claimed. See above. However, Rioux lacks a coiled section of inflation tube, an insertion tool, a separable connection between the catheter main body and the tool main body, and a selectively disconnectable bridging structure as claimed [claim 34]. Anderson, Norton and Huxel disclose examples of a coiled restraining device as discussed for claim 1 above. In this grounds of rejection, the inflation tube as taught by Rioux is modified with a coiled shape as taught by Anderson. Norton and Huxel provide further examples of a coiling structure used to restrain an endourethral implant. It is the Examiner's position that the

coiled section of Rioux in view of Anderson is capable of interacting with a constriction of the urinary tract by the sphincter muscle to restrain the catheter main body against distal movement within the urinary tract from the use position.

Rioux in view of Anderson discloses the invention substantially as claimed, see above. However, Rioux in view of Anderson lacks an insertion tool as claimed [claim 34]. Rioux calls for a "pusher" used for placing a main body (col. 9, lines 23-30), although the disclosure is silent regarding its structure. Devonec discloses:

a main body of an insertion tool, the tool main body first and second opposite ends and a length sufficient to position the first end within the urinary tract distal of the sphincter muscle while the second end is at the exterior of the urinary canal (col. 6, lines 13-31, especially lines 16, 26, Figs. 8a, 8b, 9-12, mandrel 60 and pusher 63); and

a separable connection between the catheter main body and the tool main body, the separable connection maintaining the insertion tool connected to the indwelling catheter for movement as a unit when positioning the indwelling catheter in a use position, the use position locating the distal end of the catheter main body in the bladder and the proximal end of the catheter main body adjacent to and distal of the sphincter muscle (col. 6, lines 48-54, Fig. 8a, mandrel 60 and pusher 63 joined to prosthesis 8, forming assembly for insertion into bladder 2);

the separable connection permitting selective separation of the tool main body from the catheter main body in response to proximal movement of the insertion tool when the expanded balloon restrains the catheter main body against proximal movement from the use position (col. 6, lines 59-4, Figs. 9-12, withdrawing mandrel 60

and pusher 63 from prosthesis 8. To clarify, the invention of Rioux is relied upon for a balloon as discussed, and is modified with the insertion tool as taught by Devonec.);

Regarding the limitation of a coiled section of the inflation tube winding around the insertion tool when the insertion tool is connected to the indwelling catheter, Rioux teaches an indwelling catheter and inflation tube, while Anderson provides an example of a coiled section of tube. Further, Devonec discloses an insertion tool extending through the center opening of a coiled section (cols. 5-6, lines 53-58, 66-2, Fig. 13, coil 52). In other words, Devonec teaches that mandrel 60 is placed within tubular segment 11 of prosthesis 8, which comprises a coil 52, which suggests placing an insertion tool within a coiled section. Regarding rationale and motivation to modify Rioux in view of Anderson and further in view of Devonec, see discussion of claims 1 and 10 above.

13. Claims 17, 18, 28, 29, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux et al. (US Patent 6,494,855) in view of Anderson et al. (US Patent 4,813,925), in view of Devonec (US Patent 6,290,666), further in view of C, Ewers Richard (US Patent Application Publication No. 2001/0056273, herein "Ewers").

14. Regarding claims 17, 18, 28, 29, 38 and 39, Rioux in view of Anderson in view of Devonec discloses the invention substantially as claimed, including a cord (Devonec, Figs. 8a, 8b, 9-12, removal thread 14). See above. However, Rioux in view of Anderson in view of Devonec lacks a cord extending through the interior channel of an insertion tool as claimed [claims 17, 18, 28, 29, 38 and 39]. In other words, Devonec is silent regarding the placement of removal thread 14 within the lumen of a tube. Ewers

discloses a catheter assembly suitable for placement within a urethra (¶ [0044], [0045]), further comprising a cord also extending through an interior channel to the second end of an insertion tool (¶ [0046], [0048], [0051], Figs. 3-5, suture 34 substantially extending through tube 14 to second end). To clarify, the invention of Rioux, Anderson and Devonec as discussed is modified in view of the cord positioned within the lumen of a tube as taught by Ewers. Ewers provides the advantage of a compact design avoiding interaction between pulling a cord and patient tissues. In other words, placing a cord within a tube avoids potential abrasion between a cord and the inner urethral surface. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Rioux in view of Anderson in view of Devonec as discussed with the cord extending through an interior channel as taught by Ewers in order to avoid potential abrasion.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 16 and 17 of copending Application No. 10/921,356 to Bolmsjo et al. (US Patent Application Publication No. 2005/0080399) herein "Bolmsjo '399." Although the conflicting claims are not identical, they are not patentably distinct from each other because:

17. Regarding claim 1, Bolmsjo '399 discloses an indwelling catheter to drain urine from a bladder to a location adjacent to a urinary sphincter muscle in a urinary tract which also includes a urinary canal extending from the sphincter muscle to an exterior opening, comprising:

a main body having a distal end, a proximal end and a length sufficient to position the distal end within the bladder and to position the proximal end adjacent to and distal of the sphincter muscle within the urinary tract, the main body defining an urine drainage interior passageway extending from the distal end to the proximal end (Bolmsjo '399 claim 1);

a balloon attached to the distal end of the main body, the balloon expandable in size within the bladder to maintain the distal end in the bladder and restrain the main body against proximal movement within the urinary tract from a use position, the use

position locating the distal end of the main body in the bladder and the proximal end of the main body adjacent to and distal of the sphincter muscle (Bolmsjo '399 claims 1 and 16, distal anchor comprising a balloon);

an inflation tube having a distal end, a proximal end and a length extending between the distal end proximal ends, the distal end connected to the main body, the length sufficient to extend from the main body through the urinary canal to the exterior opening when the main body is in the use position, the inflation tube and the main body defining an inflation passageway extending from the proximal end of the inflation tube to the balloon through which to deliver inflation fluid for expanding the balloon (Bolmsjo '399 claim 16); and

a coiled section of the inflation tube formed at a position along the inflation tube to locate the coiled section within the urinary canal adjacent to and proximal of the sphincter muscle when the main body is located in the use position, the coiled section interacting with a constriction of the urinary tract by the sphincter muscle to restrain the main body against distal movement within the urinary tract from the use position (Bolmsjo '399 claim 17).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Amendment

18. Objections of claims 1 and 31 applied in the Office Action dated 29 October 2007 are withdrawn in view of the supplemental amendments filed 13 June 2008.

Response to Arguments

19. Rejections of claims 1-40 and 44-48 under 35 USC § 103 in view of Rioux in view of Gellman applied in the Office Action dated 29 October 2007 are withdrawn in view of the supplemental amendments filed 13 June 2008 and the telephone interview held 3 June 2008. However, new grounds of rejection under 35 USC § 103 in view of Rioux, Anderson, Devonec and Ewers have been applied. See above.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Whalen, Mark J. et al. US 20020107540
- Ensminger; William D. et al. US 5256146
- Glassman; Jacob A. US 4501580
- Anderson, Kimberly A. et al. US 20030055313

21. Due to the new grounds of rejection presented for claims 1-40 and 44-48 not necessitated by amendment, this Office action is **non-final**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is (571)272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

//Leslie R. Deak//
Primary Examiner, Art Unit 3761
18 September 2008